VIA EMAIL ONLY

May 31, 2019

To: **All Plata Counsel**

Re: **Assessing Medical Systems for the CA Prison Health Care Receivership: CCHCS PATIENT SAFETY PROGRAM**

This letter acknowledges receipt of the final report entitled, "*Assessing Medical Systems for the CA Prison Health Care Receivership: CCHCS PATIENT SAFETY PROGRAM*" (Report), prepared by The Criminal Justice & Health Program at the University of California, San Francisco.

On August 17, 2017, the parties filed a Joint Case Management Statement, the purpose of which was to identify all issues that remained to be resolved in the case. In a section of the joint statement reflecting issues that only the PLO believed remained to be resolved, mention was made of "Problems with quality of care review and staff accountability processes: peer review, death review, annual physician evaluations, the patient safety program, and internal affairs investigations." (Joint Case Management Statement, p. 13, line 24, 8/17/2017) In response, the Receiver engaged the services of Dr. Brie Williams from the University of California, San Francisco, to examine a number of these systems and evaluate their adequacy when assessed against community practices in large healthcare organizations.

Dr. Williams and her team produced a draft report on the patient safety program, which was distributed on May 1, 2019, to the parties and the court experts for review and comment. The State chose not to submit a written comment, but orally communicated to the Receiver its agreement with the report and its recommendations.

Court Experts' Comments

The court experts submitted the following comments on May 17, 2019:

> The court experts have reviewed the Draft CCHCS Patient Safety Report by The Criminal & Health Program at UCSF. We think the report is outstanding and provides a blueprint for enhancing CCHCS' existing Patient Safety Program. We have two comments.
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> 1. We support the report's recommendation (#7) to use 602-HC appeals to identify trends or cases of concern relative to patient safety. The current taxonomy for 602-HC appeals does not facilitate identification of patient safety risks and errors. We suggest that the taxonomy for HC-602 appeals and the Incident Reporting System be aligned with one another so that trends in patient and staff reports can be analyzed and compared.

2. We strongly support the recommendation that a Director of Patient Safety position be created at each facility. Consideration should be given to including "systems engineer" as qualified training, as they typically have capacity to analyze problems and perform root cause analyses.

I agree with comment (1), and I am directing staff to explore the feasibility of the suggested alignment. I agree partially with comment (2). As discussed below, I do not believe it is necessary to create a Director of Patient Safety at every facility. I agree that the skills set for a director includes the capacity to analyze problems and, with appropriate training, to perform or facilitate root cause analyses.

Prison Law Office's Comments

The PLO submitted the following comments on May 17, 2019:

Plaintiffs agree with the draft Report and its recommendations except as discussed below:

1. **The Report should include far more detail regarding problems with current CCHCS Root Cause Analyses (RCAs), and, relatedly, what training and other steps are needed to correct those problems.**

The report directly implies there are serious problems with current CCHCS RCAs. It states, "Statewide [Patient Safety Program] stakeholders have expressed concerns about the quality of RCAs, and we share these concerns after our review of a sample of RCAs." Report at 30. It accordingly recommends training people to do better RCAs. *Id*.

However, the Report does not specify the problems with the quality of current RCAs. Unless the problems are specified, the scope and focus of the necessary training cannot be determined, or evaluated. Specifying problems is also important to establish the starting point against which evaluations of the quality of future RCAs can be compared. More generally, detail regarding effective RCAs should be included given the central importance of RCAs to the Patient Safety Program, and thus to an adequate quality improvement process for the medical care delivery system.

2. **The Report should recommend comprehensive continuing oversight of Patient Safety Program (PSP) activities including in particular of RCAs even if a local prison demonstrates proficiency in conducting RCAs, and should recommend how that oversight is to be done, with heightened requirements for the most serious cases.**

The Report recommends that "RCAs should initially be performed with mandatory [Headquarters] or regional oversight, with a focus on building

capacity at institutions and the goal of transitioning to ad hoc [Headquarters] and regional involvement if/when the institution has demonstrated proficiency." Report at 30. This recommendation implies that currently local prisons cannot adequately do RCAs on their own, an idea with which Plaintiffs whole-heartedly agree: we are deeply concerned that local prison staff, or staff at some prisons, are unable to consistently adequately identify or admit problems with their medical delivery systems, recognize and stratify concerns from patient-centric view, or identify root causes. Moreover, we believe that even if a particular prison performs proficient RCAs, that can change in very short order if a key staff member, manager, or executive leaves or is replaced, or if such a person takes a more active role than they previously had. For these reasons, there must always be multiple layers of review and accountability, and the Report should recommend that Headquarters review every RCA and other key PSP activities done at the local prisons, regardless of whether previous RCAs have been proficient, and that such reviews be documented. Relatedly, the Report should recommend that all RCAs involving the risk of or actual serious patient harm or deaths be monitored in real time [sic] Headquarters staff or an independent entity, with the ability to elevate concerns about the RCA as it is proceeding and at its conclusion to highest executive levels.

3. **The Report should include information regarding whether existing Patient Safety Program work adequately identifies and routes problems with individual staff misconduct, and recommend that every health care incident involving a risk of or actual serious harm to a patient (including deaths) be reviewed and evaluated, both initially and subsequently if new facts so require, to determine whether there was or could have been misconduct such that an investigation, and/or formal employee discipline, should be undertaken.**

Plaintiffs understand that Patient Safety Program activities focus on health system deficiencies, given the foundational precept that such deficiencies are, compared to actions of individual staff, more often the root cause of adverse events. See Report at 2. But this still means that some adverse events are caused by individual staff, including because of misconduct. We believe that the risk of staff misconduct is especially great in a prison medical care delivery system, given the animus that can or does develop toward incarcerated people including because of the custody-dominated environment, as well as the perception among many staff members that State accountability mechanisms are toothless.

CDCR has processes by which staff misconduct can be investigated and culpable staff formally disciplined, and that CCHCS staff are subject to those processes. The Report should include this fact, and that people who provide medical care, especially given the particular dynamics of providing care in

> prisons, sometimes should be investigated and disciplined due to misconduct that presented a risk of or caused serious harm to a patient. The Report should include information regarding whether the current Patient Safety Program adequately identifies and routes incidents with individual staff misconduct for investigation and discipline. It should further recommend that every health car incident involving a risk of or actual serious harm to a patient (including deaths) be specifically reviewed, both initially and subsequently if new facts so require, to determine whether an investigation and/or formal employee discipline should be undertaken.

I disagree with the PLO's first comment that the report should include more detail regarding problems with some RCAs conducted at the institution level and should specify what training and other steps are needed to correct those problems. It is clear from the report that CCHCS's statewide leadership is already aware of the opportunities to improve the quality of RCAs ("Statewide PCP stakeholders have expressed concerns about the quality of RCAs," p. 30), and CCHCS has already demonstrated its capacity for training clinical personnel to perform sophisticated, systems analysis of the sort required for RCAs ("The training of a large cadre of leadership and line staff in Lean Six Sigma, for example, demonstrates commitment to advancing institutional knowledge of quality improvement throughout the organization," p. 29). Given this existing expertise within CCHCS, there is no need for additional detail in the report. CCHCS is itself capable of developing the RCA component of the PSP.

I disagree with the PLO's second comment that the report should recommend comprehensive continuing oversight of PSP activities and should recommend how that oversight is to be done, with heightened requirements for the most serious cases. There is no evidence that the community standard for PSP implementation requires any sort of special continuing oversight over and above what an organization ordinarily does to ensure implementation of organizational policies and practices, and there is no evidence that CCHCS is not capable of making appropriate decisions regarding oversight. The report correctly recommends that there needs to be substantial oversight while an institution begins to develop its skills in producing RCAs. This is consistent with how CCHCS has approached most of its systemwide initiatives. As local expertise develops, it may be appropriate to assign greater responsibility to local leadership and clinicians, which is what the report recommends. However, given that we are just beginning to develop local PSP capacity, it is likely that there will be a very substantial period of time before we consider a substantial reduction in HQ and/or regional involvement in PSP activities.

Finally, I disagree with the PLO's third comment that the report should include information regarding the existing PSP's identification of individual staff misconduct and should recommend that every serious health care incident be reviewed for staff misconduct. As the report explains, the most fundamental premise of a patient safety program – and of modern quality improvement generally – is that the vast majority of

medical errors reflect poorly designed systems and are not the result of purely individual failures by individual practitioners (p. 2). As explained in the quote in Box 1 on page 2 of the report, "Rather than focusing corrective efforts on punishment or remediation, the systems approach seeks to identify situations or factors likely to give rise to human error, and change the underlying systems of care in order to reduce the occurrence of errors or minimize their impact on patients." A robust system of patient safety review can function only in the context of a process and culture that is fully committed to systems improvement over individual punishment. That is not to say that there will never be instances where individual staff misconduct will be identified. But to make identification of staff misconduct a special goal of health care incident review would substantially interfere with CCHCS's ability successfully to establish a patient safety and quality improvement system where clinicians and staff feel comfortable in reporting health care incidents.

Directions to Staff

I am pleased to accept the report without modification, and I commend the authors of the report for making a significant contribution to our ongoing efforts. I am also pleased to commend CCHCS staff for establishing a quality improvement and patient safety function that so clearly meets community standards. It is gratifying to see in this report such a broad endorsement of the program which I described four years ago in my *Special Report: Improvements in the Quality of California's Prison Medical Care System*, pp. 48-51 (March 2015). All of us engaged in these efforts recognize that our programs should be considered "a work in progress" (Report, p. 5); indeed, being "in progress" is one of the core features of any effective quality improvement program.

One aspect of the report – the scope of a patient safety program – recommends adopting "a broad definition [of patient safety] that defines housing infrastructure and policy, nutrition, and general prison conditions as part of medical care for incarcerated individuals and thus within the scope of patient safety." (Report, p.3) In the context of this litigation, that broad definition is not appropriate. First, in addition to the fact that the jurisdiction of the *Plata* litigation does not encompass the mental health program, the *Plata* litigation also does not encompass general prison conditions. *Plata* is not a prison conditions case; it is a quality of medical care case, and the focus of the litigation is on the delivery of medical services to patients. Second, other inmate and staff safety policies and procedures, including requirements for systematic retrospective analysis of incidents involving violence and harm, have been in place for decades within CDCR, both at the institution and HQ levels.

A second issue relating to scope involves the extent of decentralization of organizational units with independent patient safety staff. On page 6, the report describes the organizational structure of the patient safety program within the Veterans Administration healthcare system, noting that "its PSP includes staffing at the national, regional, and medical center levels." On page 9, the report implicitly

assumes that there is congruence between the three levels of organizational structure within the VA and the three levels of organizational structure within CDCR – i.e., headquarters, regional and institutional. That implicit assumption appears to be the primary basis for the recommendation that CCHCS place a Director of Patient Safety, along with related subcommittees, at every prison.

The report's implicit assumption of congruence is incorrect in the context of a patient safety program. In fact, the scope of a VA medical center is much closer to the scope of the entire CDCR system. For example, The VA's Northern California Health Care System serves over 250,000 veterans residing in 17 California counties, and the system has facilities in Sacramento, Chico, Redding, Fairfield, Vallejo, Martinez and Oakland with hundreds of providers. The center's public safety program is managed by one office with a small contingent of staff; the center has not established patient safety managers or related staff at any of its other facilities throughout the region.

I do not believe a patient safety program within CDCR can adequately perform its function with only a headquarters office dedicated to the task. However, I also do not believe it is necessary or even wise to place patient safety offices at every facility. Instead, staff should analyze actual workload and need in assessing how best to organize and staff the patient safety function. For example, it may be a good idea to place a patient safety director at CHCF, CMF, and at one or two other high-acuity, high population prisons (e.g., perhaps RJD). At other facilities, where there is not likely to be sufficient workload to justify dedication of full-time resources, it may be more appropriate to locate the function at the regional office (or retain the function primarily at headquarters). These organizational details do not detract from the core requirements of a successful program, and it does not appear there is a uniformly-established community standard for how best to organize patient safety programs in large, geographically dispersed health care organizations.

CCHCS staff is hereby directed to continue evolving our patient safety program, taking into consideration all of the recommendations contained in the report as appropriately modified by my comments regarding the scope of the program.

Sincerely,

J. Clark Kelso
Receiver